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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,472	12/29/2000	Dinesh Mody	GUID-117	7176

36154 7590 07/25/2007

LAW OFFICE OF ALAN W. CANNON
942 MESA OAK COURT
SUNNYVALE, CA 94086

EXAMINER	
SHAY, DAVID M	

ART UNIT	PAPER NUMBER
3735	

MAIL DATE	DELIVERY MODE
07/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ED

Office Action Summary	Application No.	Applicant(s)	
	09/751,472	MODY	
	Examiner	Art Unit	
	david shay	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *May 7, 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-22,25-33,40-54,58-91,97,100-107,225,229-255,282 and 284-300* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-22,25-33,40-54,58-91,97,100-107,225,229-255,282 and 284-300* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The examiner has taken official notice of various facts in the previous office action. In the instant response, applicant has not challenged these facts, and thus these officially noticed facts are taken to be admitted prior art (see MPEP 2144.03(C)). The examiner notes the submission of the terminal disclaimers in the response to the obviousness type double patenting rejections, as the disclaimers have now been processed, the rejections are withdrawn.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "inserting said ablative device through the at least one lumen having a radially asymmetric geometry"; "temperature sensor"; and the "assessing the electrical isolation..." must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to because Figures 21 and 22 have improper shading. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

With respect to Sinofsky et al, applicant appears to argue that the housing of Sinofsky et al, is the ablation device itself. If the claim is to be interpreted in this manner, it is not supported by the originally filed disclosure, as the wall of the lumen carrying the device which transports energy from the exterior of the body to the treatment site of applicant's device is not disclosed as being contained within a sheath that contacts the tissue either, thus this argument is not convincing. Applicant also asserts that the slidability of the ablating element of Sinofsky et al is

"merely an adjustment feature", however, since this "adjustment feature", allows the tissue area to be ablated to be controlled, just as in applicant's device, thus this does not serve to distinguish the instant device over that of Sinofsky et al. Next applicant asserts that the device of Sinofcky et al is "an integral handheld device and the ablation element 12, is not inserted through an ablation sheath". The examiner must respectfully disagree. In the embodiment best illustrated in Figure 3B, the ablation element (optical fiber 18A, which has "an energy delivery portion which is adapted to be coupled to a source of laser energy and emit ablative radiation in a predetermined direction" as claimed in claim 225) is clearly inserted through the ablation sheath (housing 26, which has "a proximal end portion, a distal end portion and at least one lumen having a radially asymmetric geometry and a contact surface near the distal end parallel to a longitudinal axis of the ablation sheath", note the cross section shown in phantom of Figure 2 for the radially asymmetric geometry, as claimed in claim 225). Applicant then argues, with respect to claims 293 and 297 that Sinofsky et al fail to disclose the step of maintaining alignment of the ablation means and the lumen relative to a rotational direction. The examiner must respectfully disagree. Sinofsky et al clearly show the oval cross section of the ablation sheath in Figure 4, while the complementary cross section of the passage and the fiber are shown in Figure 2, it is well understood that a "claimed invention may be anticipated or rendered obvious by a drawing in a reference, whether the drawing disclosure be accidental or intentional" (*In re Meng*, 181 USPQ 94, 97). It is inherent that an oval fiber in an oval passage will maintain rotational alignment. Applicant asserts that the reference by Sinofsky et al to emitting light in a circular pattern teaches against rotational alignment. The examiner must respectfully disagree. Any light emitter regardless of shape, will emit light in a circular pattern along its length. A square cross

section fiber, for example, would still emit light from the corners thereof, and thus output light in a circular pattern. Therefore, this disclosure by Sinofsky et al does nothing to teach against the oval shape shown in the drawings thereof. Thus this argument is not convincing.

With regard to the rejection involving Cox et al (WO '187), the examiner apologizes for the confusion caused thereby. Due to a "cut and paste" error the examiner inadvertently included portions of the motivation statement which were not officially noticed facts in the recitation of the facts that were actually officially noticed. The rejection has been corrected to omit the erroneously included material. However, the examiner does not agree that the use of a key is not a notorious means of recognizing the orientation of a device. Applicant appears to argue that, since there are other means of determining the orientation of a device, the use of a key cannot be used in such a manner. The examiner cannot agree. The use of the spatial irregularity of a device (or "key") as an alignment device would unquestionably be recognized as a means for recognizing alignment by a surgeon. The level of skill of a surgeon is very high, requiring not only 12 years of primary and secondary school, but 4 years of college, 4 more years of medical school, and additional years as an intern before qualifying as surgeon. And, as set forth in KSR International Co. v Teleflex Inc. 82 USPQ2d 1385, 1397 (Supreme Court, 2007), "Common sense teaches, however, that familiar items may have obvious uses beyond their primary purposes,... A person of ordinary skill is also a person of ordinary creativity, not an automaton." Therefore, just as it is a fact that the surgeon of ordinary skill understands that it is necessary to tie his shoes before beginning an operation, even though there is no disclosure of doing so in any of the references of record, similarly, the surgeon understands that a spatial irregularity is a means for determining or maintaining orientation of a device, just as it is when using a pair of

binoculars. The examiner respectfully point out that applicant appears to have misconstrued the taking of official notice of some facts. Applicant appears to be under the impression that the examiner has taken official notice of the obviousness of employing certain notorious structures and practices associated therewith. The examiner has done nothing of the kind. The examiner has taken notice of various facts: that sensing contact is notorious in the art of ablating in sensitive organs such as the heart; that sensing temperature in ablation procedures is notorious in the art; and that applying energy to assure that the ablation has been effective is notorious in the art of ablating in sensitive organs such as the heart. It is abundantly clear that these notorious expedients, which are used to prevent patient death or the need for redoing the surgery, are factual items, and while the obviousness of using them is not, the obviousness has not been officially noticed, although the obviousness of employing the officially noticed facts has been discussed in the motivation statement.

Continuing, applicant asserts that "it is improper to combine the directional ablation features of the present invention with the disclosure of Cox et al..." The examiner must respectfully point out that both Cox et al and Sinofsky et al teach the desirability of providing directionalization of the ablation energy. Therefore, it is not necessary to combine "the directional ablation features of the present invention" with Cox et al to meet the claims at bar. It is only necessary to combine the applied references as the examiner has done.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The amendment filed February 7, 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall

introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "wherein said energy delivery portion is locatable at any position within said distal end portion to delivery ablative energy through said any position".

Applicant is required to cancel the new matter in the reply to this Office Action.

Claims 107 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed disclosure is silent on "wherein said energy delivery portion is locatable at any position within said distal end portion to delivery ablative energy through said any position".

Claim 106 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Roth et al.

Claim 106, 107, 225, 240, 243, 246, 248, 249, 253, 293-295, and 297 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Sinofsky et al.

See Figures 1-7 and column 1, line 34 to column 4, line 25, the non-circular cross section being illustrated in Figure 2, the insertion of the optical fiber occurring e.g. during the manufacture of the device.

Claims 1, 5, 9-11, 14-16, 25-33, 43-54, 58-64, 71, 72, 86, 87, 89-91, 97, 100-104, 296, 298, and 299 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarek et al in combination with Sinofsky et al. Bednarek et al teach a method such as claimed (see Figures 1-8 and column 12, lines 15-29) except the maintaining of rotational alignment. Sinofsky et al teach a cardiac ablation device employing a slidably positionable ablation element with a rotationally

asymmetric cross section positioned in sheath in a lumen with a complimentary shape wherein the energy can be directionalized. It would have been obvious to the artisan of ordinary skill to employ the rotationally asymmetric cross section lumen and ablative element of Sinofsky et al in the method of Bednarik et al, since this would enable less energy to be used in the procedure, since more of it would be directed towards the tissue while assuring that the operative direction could be reliably pointed towards the tissue of interest, or to include the various types of ablation energy and the various procedural steps of Bednarik et al in the method of Sinofsky et al, since the various energies are equivalents, as taught by Bednarik et al and Sinofsky et al do not elucidate the procedural steps required to approach the heart intravenously, to employ the jugular vein, since this is a large vessel in the neck, and to configure the ablative element to directionalize the energy or employ an cryosurgical element, since this does not manipulatively affect the method, thus producing a method such as claimed.

Claims 6-8, 12, 13, 17-22, 40-42, 70, 78, 79, 105, 225, 229-242, 244, 245, 247, 250-252, 254, 255, 282, 284-292, and 300 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarek et al in combination with Sinofsky et al as applied to claims 1, 5, 9-11, 14-16, 25-33, 43-54, 58-64, 71, 72, 86, 87, 89-91, 97, 100-105, 296, 298, and 299 above, and further in combination with Cox et al (WO '187) and the admitted prior art of simplifying the procedure, as simplification is desirable; employing a key to enable the surgeon to recognize the orientation of the surgical device, since this is a notorious orientation indicator in the art; to sense the temperature, since this notorious in ablation systems; to sense contact between the device and the tissue to be ablated, since this is notorious for ablating in sensitive organs such as the heart; and to apply energy to assure that the ablation has been effective; and performing a portion of a

bypass graft procedure before or after forming one lesion, since bypass procedures are sometimes performed in conjunction with ablation procedures. Cox et al (WO '187) teach the equivalence of laser, ultrasound, microwave, and cryosurgical energies as means of ablation, ablating tissue of the heart through a hole in the chest wall, use of a malleable end which can be pre-shaped; use of a sheath with a cut out window; and various manipulations of the device including ablating around the pulmonary vein, ablating on the epicardium, and positioning the device in three or more positions. It would have been obvious to the artisan of ordinary skill to employ the maze procedure and ablation means of Cox et al (WO '187) in the combined method of Bednarek et al in combination with Sinofsky et al, or to employ the particular ablation steps of the combined teachings of Bednarek et al in combination with Sinofsky et al in the method of Cox et al (WO '187) since Cox et al (WO '187) teach no particular form for the non-cryogenic ablation elements; to employ the various non cryogenic directional ablation element features claimed since these are merely a matter of choice and provides no unexpected result and are known means for providing the desirable functions of Cox et al (WO '187), such as directionality with these equivalent forms of ablation energy discussed by Cox et al (WO '187); to include a cutting member on the distal end of the sheath, since this would allow the cut to be made without introducing an additional tool, thus simplifying the procedure, as simplification is desirable, official notice of which is hereby taken; as well as to position the device adjacent to or in contact with the oblique or transverse sinuses as these are both structures associated with pulmonary veins and would be contacted in conjunction with the procedure shown in figure 21 of Cox et al (WO '187); to employ a key to enable the surgeon to recognize the orientation of the surgical device, since this is a notorious orientation indicator in the art; to sense the temperature, since

this notorious in ablation systems; to sense contact between the device and the tissue to be ablated, since this is notorious for ablating in sensitive organs such as the heart; to apply energy to assure that the ablation has been effective since this is also notorious in the art; official notice of all of these having already been taken and to perform a portion of a bypass graft procedure before or after forming one lesion, since bypass procedures are sometimes performed in conjunction with ablation procedures official notice of which is hereby taken thus producing a method such as claimed.

Claims 70-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarek et al in combination with Sinofsky et al and Cox et al (WO '187) as applied to claims 5-8, 12, 13, 17-22, 25-33, 40-42, 46-54, 58-72, 78, 79, 105, 225, 229-242, 244, 245, 247, 250-252, 254, 255, 282, 284-292, and 300 above, and further in combination with Swanson et al. Swanson et al teach using temperatures sensors to control ablation and electrodes to pace, map, etc. the heart in a maze procedure wherein the pulmonary vein is encircled. It would have been obvious to the artisan of ordinary skill to employ the sensors and the pulmonary vein encircling device in the combined method of Bednarek et al in combination with Sinofsky et al and Cox et al (WO '187), since this would enable the performance of beneficial cardiac procedures such as maze or to employ the longitudinally translatable ablation element of the combined method of Bednarek et al in combination with Sinofsky et al and Cox et al (WO '187) in the method of Swanson et al, since this can create longer lesions with a single ablation element, this producing a method such as claimed.

Claims 80-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarek et al in combination with Sinofsky et al and Cox et al (WO '187) as applied to claims 5-8, 12, 13,

17-22, 25-33, 40-42, 46-54, 58-72, 78, 79, 105, 225, 229-242, 244, 245, 247, 250-252, 254, 255, 282, 284-292, and 300 above, and further in view of Kesten et al. Kesten et al teach delivering ablation devices with a pre-shaped sleeve to reach the ventricles via peripheral veins. It would have been obvious to the artisan of ordinary skills to employ the sheath, delivering route, and treatment region of Kesten et al in the combined method Bednarek et al in combination with Sinofsky et al and Cox et al (WO '187) or to employ the directional slidable probe in a sheath of the combined method of Bednarek et al in combination with Sinofsky et al and Cox et al (WO '187) in the method of Kesten et al, since this would allow the treatment of an elongated area without repositioning the device and in either case to treat one of the atria or ventricles since these chambers are the site of beneficial treatments, official notice of which has already been taken and to employ an alternate access route such as the jugular or subclavian vein, since these are recognized catheter insertion routes in the art, official notice of which has already been taken, thus producing a method such as claimed.

Claims 106 and 107, are rejected under 35 U.S.C. 102(b) as being 103(a) as being unpatentable over Bednarek et al in combination with Sinofsky et al. See Figures 1-8 and column 5, line 15 to column 13, line 5, especially column 9, line 54 to column 12, line 15.

Applicant's arguments filed July 17, 2006 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

Applicant's arguments with respect to claims 106 and 107 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed May 7, 2007 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on Monday, Tuesday, Wednesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330